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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/720,639

05/16/2001

Nissim Darvish

20066.73

3851

54042

7590

06/20/2007

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

06/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/720,639

Applicant(s)

DARVISH ET AL.

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 10-15, 55, 56, 59-64, 151-177, 205 and 206 is/are pending in the application.
- 4a) Of the above claim(s) 152-154, 156-160, 165 and 169-171 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 7, 55 and 56 is/are allowed.
- 6) ☒ Claim(s) 10-15, 59-64, 151, 155, 161-164, 166-168, 172-177, 205 and 206 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/20/07, 1/8/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 205 and 206 are rejected under 35 U.S.C. 102(b) as being anticipated by Whigham et al (4821724). Whigham shows in figure 4 a multiphasic single pulse/stimulus that has an overall duration greater than 8 ms from a portion of the signal that initiates the action potential. It is noted that the stimulus is 0.5 msec and the postcharge is 8 msec (e.g. col. 6 and 12).

Claims 10-15, 59-64, 151, 155, and 177 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito (JP62-275471). Saito shows in figure 4 and discusses the use of a 20 ms pacing pulse (e.g. page 3, the last line of the translation) to increase cardiac output where the pulses can be biphasic (e.g. page 4 of the translation). In addition, figure 4 shows approximately four equal pulses having a 50% duty cycle delivered over 20 msec, and therefore the pulse duration is seen to be approximately 3 msec. Finally, since the pulses are meant to increase pumping output to normal (e.g. page 2 of the translation) and since the pacing pulses cause a contraction and are of a similar duration as the applicants, the pulses of Saito will modify a characteristic of pulsatile flow, increase contractility by at least 10% relative to a 2ms duration pulse, and engenders a redistribution of cardiac muscle mass.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 164, 166, 172-174, and 176 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saito. Saito senses R waves (electrophysiological signals, MAPs) and operates in the demand mode (e.g. page 5) to determine when the heart is not beating properly (bradyarrhythmia) to deliver the pacing signal and therefore senses a demand for enhancement of hemodynamic performance and modifies the signal by delivering the signal or not delivering the pacing signal.

In the alternative, Saito discloses the claimed invention except for sensing a demand or MAP/electrophysiological signal representative of the activity of the heart for enhancement to convey the pacing signal (claims 164, 166, 172-174) or detecting a possible arrhythmia to modify the pacing signal. It would have been obvious to one having ordinary skill in the art at

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the time the invention was made to incorporate into the pacing system and method as taught by Saito the use of sensing a demand or MAP/electrophysiological signal representative of the activity of the heart for enhancement to convey the pacing signal (claims 164, 166, 172-174) or detecting a possible arrhythmia to modify the pacing signal since it was known in the art that pacing systems and methods use: sensing a demand or MAP/electrophysiological signal representative of the activity of the heart for enhancement to convey the pacing signal to allow the pacemaker to easily and conventionally determine when the heart is not and is functioning properly to deliver or not deliver the pacing signal when needed; and detecting a possible arrhythmia to modify the pacing signal to allow the system to adjust the signal to the demands and needs of the patient based on the patients particular condition or history.

Claims 161-163, 167, 168, and 175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito. Saito discloses the claimed invention except for applying electrodes in different chambers (endocardially) and applying a plurality of waveforms/extended pacing signals to the different electrodes (claims 161-163 and 168), in the absence of demand conveying lower energy signals (claim 167), and using bipolar electrodes to receive the electrophysiological signal (claim 175). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing system and method as taught by Saito, with applying electrodes in different chambers (endocardially) and applying a plurality of waveforms/extended pacing signals to the different electrodes, in the absence of demand conveying lower energy signals, and using bipolar electrodes to receive the electrophysiological signal since it was known in the art that pacing systems and methods use: applying electrodes in different chambers (endocardially) and applying a plurality of waveforms/extended pacing

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signals to the different electrodes to provide a dual chamber pacemaker that can deliver the signals directly to the chambers and allow electrical stimulation and treatment of both chambers to treat both atrial and ventricular problems of the patient; in the absence of demand conveying lower energy signals to allow the heart to strengthen itself by beating on its own and prevent the loss of battery power when the extended pacing signal is not needed; and using bipolar electrodes to receive the electrophysiological signal to provide a bipolar signal that more accurately reflects the electrical activity of that particular heart chamber.

Allowable Subject Matter

Claims 6, 7, 55, and 56 are allowed.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

6/17/07

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